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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,873

08/28/2003

Amnon Peled

26732

7262

7590

08/06/2007

Martin D. Moynihan  
PRTSI, Inc.  
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EXAMINER

HISSONG, BRUCE D

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

08/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/649,873	Applicant(s) PELED ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-54 and 56-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-52 and 56-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-54, 77-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence comparison</u>                |

## DETAILED ACTION

### **Formal Matters**

1. Applicant's response to the office action mailed on 11/1/2006, including arguments/remarks and amendments to the claims and specification, was received on 5/1/2007 and has been entered into the record.

2. Applicants have cancelled claim 55 and added new claims 77-82. Therefore, claims 1-54 and 56-82 are currently pending, with claims 1-52 and 56-76 withdrawn as non-elected subject matter, and claims 53-54 and 77-82 the subject of this office action.

### **Specification**

Objection to the specification for improper use of trademarks, as set forth on page 3 of the office action mailed on 11/1/2006, is withdrawn in response to Applicants' amendments to the specification to properly identify trademarks.

### **Claim Objections**

Objection to claims 53-54 for depending from non-elected claim 1, as set forth on page 3 of the office action mailed on 11/1/2006, is withdrawn in response to Applicants' amendments to incorporate the limitations of claim 10 into independent claim 53.

### **Claim Rejections - 35 USC § 112, first paragraph - enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-54 remain rejected, and new claims 77-82 are also rejected under 35 USC § 112, first paragraph, regarding lack of enablement for a method of treating any disease not

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mediated by IL-8, by administration of any peptide other than that of SEQ ID NO: 64 (BKT-45), as set forth on pages 4-5 of the prior office action mailed on 11/1/2006.

In the response received on 5/1/2007, the Applicants argue that the peptides of the instant invention were identified by screening for the ability to bind chemokines and modulate the activity of said chemokines. The peptides identified in this manner are designated Family 1 or Family 2 peptides based on common structural features and common sequence characteristics, and therefore the common structural features of these peptide sequences can reasonably be assumed to be involved in the modulatory activity of these peptides. The Applicants further argue that each member of the Family 2 peptides binds IL-8, MCP-1, and/or MIG. Therefore, a person of ordinary skill in the art would recognize that peptides sharing these structural features (two adjacent histidine residues, and at least two amino acids selected from P, T, L, R, W, and F, and an overall positive charge) would exhibit the same binding and inhibitory activities towards these chemokines, and therefore would be able to practice the claimed method without undue experimentation.

These arguments have been fully considered and are not persuasive. The specification provides guidance and examples of a family of peptides, the Family 2 peptides, which are capable of binding MCP-1, IL-8, MIG, SDF-1 $\alpha$ , and/or eotaxin (Table 3 of specification and Table 1 of the Declaration under 37 CFR 1.132). The specification also teaches that the Family 2 member BKT-45 (SEQ ID NO: 46) antagonizes the activity of IL-8 and MIG (Table 4 of specification), and Table 2 of the 132 Declaration shows that the BKT-46 peptide (SEQ ID NO: 76) inhibits MIG, MCP-1, and SDF-1 $\alpha$  activity. As set forth on page 5 of the office action mailed on 11/1/2006 regarding the disclosure of Hay et al, inhibition of a particular chemokine would be usefully only under conditions where it is the only chemokine involved. In conditions characterized by secretion of multiple chemokines, other chemokines would also have to be inhibited for effective treatment. The specification provides guidance and examples showing peptide inhibitors capable of inhibiting only two of the recited chemokines, and therefore a person of ordinary skill in the art would not be able to predict how to treat a disorder mediated through MCP-1 by administration of BKT-45, or treat IL-8-mediated disorders by administration of BKT-46. Thus, the specification is enabling for methods of inhibiting IL-8- and MIG-dependent disorders by administration of BKT-45, and inhibition of MCP-1- and MIG-dependent disorders by administration of BKT-46.

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Furthermore, as currently written the breadth of the claims is still excessive regarding the claimed peptides. The claims read on all possible peptides, of any length, that are positively charged, *comprises* two adjacent histidine residues, *comprise* at least two amino acids selected from P, T, L, R, W, and F, and *comprise* a peptide up to about 20 amino acids in length, or from about 10 to 20 amino acids in length, or about 12 amino acids in length. The open-ended language of the claims therefore encompasses any polypeptide with two adjacent histidines, and at least two of amino acids P, T, L, R, W, and F in any position within the polypeptide, as long as the peptide further comprises any peptide of up to about 20 amino acids in length, 10 to 20 amino acids in length, or about 12 amino acids in length. Because the claims read on a method of administering a large number of potential peptides/polypeptides defined only by the presence of particular amino acids, a person of ordinary skill in the art would not be able to predict which of the many possible polypeptides/peptides would function as an inhibitor of IL-8, MCP-1, and/or MIG. Indeed, Applicants state on page 19 of the response received on 5/1/2007 that only a fraction of the screened peptides were capable of binding a chemokine. Such predictions would require further, undue experimentation, and therefore while the specification is enabling for methods of administering the Family 2 peptides of Table 3 of the specification, the specification does not provide the necessary guidance and examples needed to practice the claimed invention in a manner commensurate with the full scope of the claims.

**Claim Rejections - 35 USC § 112, first paragraph – written description**

**Rejections withdrawn**

Rejection of claims 53-54 under 35 USC § 112, first paragraph, regarding lack of written description for the genus of diseases that can be treated by the claimed method, as set forth on page 7 of the prior office action mailed on 11/1/2006, is withdrawn in response to Applicants' cancellation of claim 55, and amendment of independent claim 53 to read on diseases modulated by binding of a chemokine to a chemokine receptor wherein said chemokine is selected from the group consisting of IL-8, MCP-1, and MIG.

**Rejections maintained**

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Claims 53-54 remain rejected, and new claims 77-82 are also rejected under 35 USC § 112, first paragraph, regarding lack of written description for the genus of peptide inhibitors comprising two adjacent histidines, at least two amino acids selected from P, T, L, R, W, and F, and featuring an overall positive charge, as set forth on page 6 of the prior office action mailed on 11/1/2006.

In the response received on 5/1/2007, the Applicants argue that the claimed genus of peptide inhibitors is defined by common structural features, such as the presence of two adjacent histidine residues, and the specification discloses a correlation of structure with the ability to bind chemokines and inhibit chemokine activity. Furthermore, the Applicants argue the claims have been amended to recite inhibition as the type of modulation exhibited by the claimed peptides. Because of the disclosure of partial structure, correlation between structure and function, and recitation of a specific function (inhibition of chemokine activity), the Applicants argue that the specification adequately describes the claimed genus.

These arguments have been fully considered and are not persuasive. As set forth *supra*, due to the open-ended language of the claims, the claimed genus can comprise any polypeptide, of any size, as long as that polypeptide *comprises* two adjacent histidines, *comprises* at least two amino acids selected from P, T, L, R, W, and F, and further *comprises* a peptide of about 20 amino acids, or 10 to 20 amino acids, or about 12 amino acids. The disclosure of a correlation between the *partial* structure of two adjacent histidine residues and the function of chemokine inhibition is insufficient by itself to adequately describe the claimed genus of peptides. One of ordinary skill in the art would not expect that every polypeptide with adjacent histidine residues and at least two amino acids selected from P, T, L, R, W, and F would function as an inhibitor of IL-8, MCP-1, or MIG. Although the specification does disclose examples in Table 3, there is no teaching or description of critical sequences or size requirements for the claimed peptides. For examples, must the amino acids selected from P, T, L, R, W, and F be adjacent to or near the adjacent histidine residues, or can they be anywhere within a polypeptide? Additionally, the claims read on a peptidic chemokine inhibitor that comprises a peptide up to about 20 amino acids in length, or 10 to 20 amino acids in length, or about 12 amino acids in length. There is no recited or disclosed sequences requirements for these peptides, and therefore the claimed peptidic chemokine inhibitors can comprise any polypeptide with adjacent histidines, at least two amino acids selected from P, T, L, R, W, and

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F, and virtually any peptide sequence, as long as that peptide is about 20 amino acids in length, or 10 to 20 amino acids in length, or about 12 amino acids in length.

Furthermore, the claims are drawn to peptide inhibitors for chemokines selected from the group consisting of IL-8, MCP-1, and MIG. The specification and/or submitted 1.132 declaration show examples of two peptide inhibitors (BKT-45/SEQ ID NO: 46 and BKT-46/SEQ ID NO: 76), which are capable of inhibiting chemokine activity. Both BKT-45 and BKT-46 inhibit MIG activity, while only BKT-45 inhibits IL-8 activity, and only BKT-46 inhibits MCP-1 activity. Thus, Applicants have shown only one example of a peptide capable of inhibiting IL-8, and only one capable of inhibiting MCP-1. These examples of two single peptides are insufficient to adequately described the claimed genus of peptide inhibitors.

Therefore, due to the open-ended language of the claims that read on a large genus of polypeptides, a correlation of *partial* structure with function, and the paucity of disclosed examples of peptides capable of antagonizing IL-8, MCP-1, and/or MIG activity, the claimed genus of peptide chemokine inhibitors has not been adequately described in the instant application.

**Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Rejections withdrawn**

1. Rejection of claims 53-54 under 35 USC § 112, second paragraph, as being indefinite regarding the phrase "and/or", as set forth on page 7 of the prior office action mailed on 11/1/2006, is withdrawn in response to Applicants' amendments to claim 53 to delete the phrase.

2. Rejection of claims 53-54 under 35 USC § 112, second paragraph, as being indefinite regarding the phrase "composed", as set forth on page 7 of the prior office action mailed on 11/1/2006, is withdrawn in response to Applicants' amendments to claim 53 to recite a peptide that "comprises" two adjacent histidines, and "comprises" at least two additional amino acids selected from P, T, L, R, W, and F.

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3. Rejection of claims 53-54 under 35 USC § 112, second paragraph, as being indefinite regarding the phrases "modulates", "modulation", and "modulator", as set forth on page 8 of the prior office action mailed on 11/1/2006, is withdrawn in response to Applicants' amendments to the claims to recite "inhibits", "inhibition", and "inhibitor" in place of "modulates", "modulation", and "modulator", respectively.

4. Rejection of claim 54 under 35 USC § 112, second paragraph, as lacking antecedent basis for the phrase "the chemokines", as set forth on page 8 of the prior office action mailed on 11/1/2006, is withdrawn in response to Applicants' amendments to the claim to delete the phrase "the chemokines".

Rejections necessitated by amendment

5. Claims 53-54 and 77-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 53 recites the acronyms IL-8, MCP-1, and MIG. Acronyms must be defined upon their first use in a claim.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejections maintained

1. Claims 53-54 remain rejected, and new claims 77-78 are also rejected under 35 USC § 102(b) as being anticipated by Eriksson *et al* ("Eriksson" – US 5,840,693), as set forth on pages 9-10 of the office action mailed on 11/1/2006.



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The claims of the instant invention are drawn to a method of treating a disease by administration of a peptide chemokine inhibitor, wherein said peptide chemokine inhibitor comprises at least two adjacent histidine residues, and further comprises at least two amino acids selected from the group consisting of P, T, L, R, W, and F, exhibits a positive charge, and comprises a peptide up to about 20 amino acids in length (claim 53), or from about 10 to about 20 amino acids in length (claim 77), or about 12 amino acids in length (claim 78). The claims further recite the claimed method of treatment wherein the peptide chemokine inhibitor binds a chemokine, thereby inhibiting activity of the chemokine by inhibiting binding of the chemokine to its receptor.

As set forth in the previous office action, Eriksson teaches a polypeptide comprised of the amino acids P, T, L, R, W, and F and two adjacent histidine residues. Eriksson also teaches administration of this polypeptide for treatment of various diseases.

In the response received on 5/1/2007, the Applicants argue that the disclosure of Eriksson does not meet the limitations of the instant claims because the currently amended claims are drawn to a peptide chemokine inhibitor which comprises a peptide of about 20 amino acids, or 10 to 20 amino acids, or about 12 amino acids. Because the polypeptide disclosed by Eriksson is much larger, and the claimed peptides are no more than 20 amino acids, the polypeptide taught by Eriksson cannot meet the limitations of the claims.

These arguments have been fully considered and are not persuasive. Due to the open-ended language of the claims, which recite a peptide inhibitor that *comprises* at least two adjacent histidine residues, and *comprises* at least two amino acids, the polypeptide of Eriksson meets these limitations. Furthermore, because the instant claims recite a peptide inhibitor which comprises a peptide of up to about 20 amino acids in length (or 10 to 20 amino acids, or up to 12 amino acids as recited in claims 77-78, respectively). Contrary to the Applicants assertion that the claimed peptides are no more than 20 amino acids in length, the open-ended language of the claims merely requires the claimed peptides to comprise a 20 amino acid, 10 to 20 amino acids, or a 12 amino acid peptide. Thus, any polypeptide/peptide sequence with two adjacent histidines, at least two of P, T, L, R, W, and F, and further comprising any 20 amino acid sequence (or 10 to 20 amino acid sequence, or 12 amino acid sequence) meets the limitations of the claims. Although the claims recite "up to 20" the claims also recite "comprising" which is open-ended. Therefore, due to this, the protein can be larger than 20 amino acids, or 12 to 10 amino acids, or 12 amino acids. If Applicants wish to limit the protein

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size to only about 20 amino acids (or 10 to 20, or 12 amino acids), they should consider using "consisting of" language – ***without adding new matter***.

Regarding an overall positive charge for the molecule, it is noted that the USPTO does not have the facilities for testing the overall charge of the peptide of Eriksson, and therefore the burden is on the applicant to show a novel and unobvious difference between the claimed peptidic chemokine modulators and the peptide of Eriksson. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the polypeptide taught by Eriksson meets these claim limitations, and because Eriksson teaches administration of this polypeptide for treatment of disease, Eriksson teaches a method of treatment that meets the limitations of claims 53 and 77-78.

Furthermore, although Eriksson does not explicitly teach binding of this polypeptide to any chemokine resulting in subsequence inhibition of chemokine-chemokine receptor binding and inhibition of activity, it is noted that the Applicants previously argue that that the instant specification disclosed a correlation between the partial structure of two adjacent histidine residues and the function of chemokine inhibition (see page 22 of the arguments/remarks received on 5/1/2007). Therefore, it would be expected, in the absence of evidence to the contrary, that the polypeptide of Eriksson, by virtue of comprising at least two adjacent histidine residues at least two amino acids selected from P, T, L, R, W, and F, would bind a chemokine and inhibit activity of said chemokine by inhibition of binding to the appropriate chemokine receptor. Thus, Eriksson also meets the limitations of claim 54.

2. Claims 53-54 remain rejected, and new claims 77-78 are also rejected under 35 USC § 102(e) as being anticipated by Kovesdi *et al* ("Kovesdi" – US 2003/0027751 A1), as set forth on pages 1011 of the office action mailed on 11/1/2006.

The subject matter of the claims of the instant invention is discussed *supra*. As set forth in the previous office action, Kovesdi teaches a polypeptide comprised of the amino acids P, T, L, R, W, and F and two adjacent histidine residues, and also teaches administration of this polypeptide for treatment of various diseases.

In the response received on 5/1/2007, the Applicants argue that the disclosure of Kovesdi does not meet the limitations of the instant claims because the currently amended claims are drawn to a peptide chemokine inhibitor which comprises a peptide of about 20 amino acids, or 10 to 20 amino acids, or about 12 amino acids. Because the polypeptide disclosed by

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Kovesdi is much larger, and the claimed peptides are no more than 20 amino acids, the polypeptide taught by Kovesdi cannot meet the limitations of the claims.

These arguments have been fully considered and are not persuasive. Due to the open-ended language of the claims, which recite a peptide inhibitor that *comprises* at least two adjacent histidine residues, and *comprises* at least two amino acids, the polypeptide of Kovesdi meets these limitations. Furthermore, because the instant claims recite a peptide inhibitor which comprises a peptide of up to about 20 amino acids in length (or 10 to 20 amino acids, or up to 12 amino acids as recited in claims 77-78, respectively). Contrary to the Applicants assertion that the claimed peptides are no more than 20 amino acids in length, the open-ended language of the claims merely requires the claimed peptides to comprise a 20 amino acid, 10 to 20 amino acids, or a 12 amino acid peptide. Thus, any polypeptide/peptide sequence with two adjacent histidines, at least two of P, T, L, R, W, and F, and further comprising any 20 amino acid sequence (or 10 to 20 amino acid sequence, or 12 amino acid sequence) meets the limitations of the claims. Although the claims recite "up to 20" the claims also recite "comprising" which is open-ended. Therefore, due to this, the protein can be larger than 20 amino acids, or 12 to 10 amino acids, or 12 amino acids. If Applicants wish to limit the protein size to only about 20 amino acids (or 10 to 20, or 12 amino acids), they should consider using "consisting of" language – ***without adding new matter***.

Regarding an overall positive charge for the molecule, it is noted that the USPTO does not have the facilities for testing the overall charge of the peptide of Kovesdi, and therefore the burden is on the applicant to show a novel and unobvious difference between the claimed peptidic chemokine modulators and the peptide of Kovesdi. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the polypeptide taught by Kovesdi meets these claim limitations, and because Kovesdi teaches administration of this polypeptide for treatment of disease, Eriksson teaches a method of treatment that meets the limitations of claims 53 and 77-78.

Furthermore, although Kovesdi does not explicitly teach binding of this polypeptide to any chemokine resulting in subsequence inhibition of chemokine-chemokine receptor binding and inhibition of activity, it is noted that the Applicants previously argue that that the instant specification disclosed a correlation between the partial structure of two adjacent histidine residues and the function of chemokine inhibition (see page 22 of the arguments/remarks received on 5/1/2007). Therefore, it would be expected, in the absence of evidence to the

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contrary, that the polypeptide of Kovesdi, by virtue of comprising at least two adjacent histidine residues at least two amino acids selected from P, T, L, R, W, and F, would bind a chemokine and inhibit activity of said chemokine by inhibition of binding to the appropriate chemokine receptor. Thus, Kovesdi also meets the limitations of claim 54.

Rejection necessitated by amendment

3. Claims 80-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Gyuris *et al* (US 2003/0166004). The subject matter of the instant application is discussed *supra*. Claims 80-81 are further drawn to the method of treating a disease by administering a peptide chemokine inhibitor, wherein said peptide has at least 90%, or about 95% sequence homology to the peptides of SEQ ID NOs 59, 64, 65, 76, 79, 126, 7, or 9.

Gyuris *et al* teaches a polypeptide, SEQ ID NO: 126, which exhibits 90.5% identity to SEQ ID NO: 79 of the instant invention (see attached sequence comparison). The peptide of Gyuris *et al* is disclosed as an endothelial cell binding protein (ECBP – see abstract and claim 3), and can be administered in methods of treating various types of disease (see claims 42-43). Although Gyuris *et al* does not specifically recite a method of treating a disease modulated through or caused by binding of IL-8, MCP-1, and/or MIG to the appropriate chemokine receptor, it is noted that because the polypeptide of Gyuris *et al* comprises a peptide that is more than 90% homologous to that of SEQ ID NO: 76 of the instant application. Thus it would be expected, in the absence of evidence to the contrary, that the polypeptide of Gyuris would bind the chemokine receptor for IL-8, MCP-1, and/or MIG, and therefore be effective in treating diseases modulated through or caused by binding of IL-8, MCP-1, and/or MIG to the appropriate receptor. Interpreted in this manner, the disclosure of Gyuris *et al* teaches a method of treating a disease modulated through IL-8, MCP-1, and/or MIG, and because the sequence of Gyuris *et al* is at least 90% homologous to SEQ ID NO: 79 of the instant invention, Gyuris *et al* anticipates claim 80 of the instant invention. Furthermore, because 90.5% can be considered to be "about" 95%, Gyuris *et al* also anticipates claim 81 of the instant application.

Conclusion

No claim is allowable.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH  
Art Unit 1646

/Robert S. Landsman/  
Primary Examiner, Art Unit 1647

SEQUENCE COMPARISON - 10/649.873

RESULT 3

US-10-286-457-126

; Sequence 126, Application US/10286457

; Publication No. US20030166004A1

; GENERAL INFORMATION:

; APPLICANT: JENO GYURIS et al.

; TITLE OF INVENTION: ENDOTHELIAL-CELL BINDING PEPTIDES FOR DIAGNOSIS  
AND THERAPY

; FILE REFERENCE: GPCI-P01-178

; CURRENT APPLICATION NUMBER: US/10/286,457

; CURRENT FILING DATE: 2002-11-01

; PRIOR APPLICATION NUMBER: 60/334822

; PRIOR FILING DATE: 2001-11-01

; NUMBER OF SEQ ID NOS: 684

; SOFTWARE: PatentIn version 3.1

; SEQ ID NO 126

; LENGTH: 12

; TYPE: PRT

; ORGANISM: Artificial Sequence

; FEATURE:

; OTHER INFORMATION: artificial sequence isolated from random peptide  
libraries, based on

; OTHER INFORMATION: ability to selectively bind to endothelial cells

US-10-286-457-126

Query Match 90.5%; Score 67; DB 4; Length 12;

Best Local Similarity 100.0%; Pred. No. 0.0011;

Matches 11; Conservative 0; Mismatches 0; Indels 0;

Gaps 0;

QY 1 LLADTTHHRPW 11

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Db 1 LLADTTHHRPW 11